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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/624,946	07/25/2000	Mark I. Greene	PENN-0708	7480

7590 11/06/2002

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EXAMINER
TUNG, JOYCE

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 11/06/2002 16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/624,946	Greene et al.
Examiner	**Art Unit**
Joyce Tung	1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 23, 2002*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *5-11* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *5-11* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *5-11* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/23/2002 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 5-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly added language "consisting of a single heavy or light chain Fv" in claims 5 and 8, and "the epitope detector is a universal epitope detector" has no support in the specification. Thus, it constitutes new matter.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 5-7 are vague and indefinite because the preamble is directed to a system for quantifying molecules expressing a selected epitope, while the system as claimed does not have an element for quantifying the molecules expressing a selected epitope.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 5-6 and 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. (Jpn. J. Cancer Res., 1985, Vol. 86, pg. 885-889) in view of Eberwine et al. (5,922,553).

Suzuki et al. disclose a method of detecting antigens in sera. The method involves using a first monoclonal antibodies to bind the circulating antigens is immobilized. A second monoclonal antibody biotinylated binds to the antigen (See pg. 885, the Abstract). The second monoclonal antibody is attached to a biotinylated DNA (See pg. 885, the Abstract). So the second monoclonal antibody acts as an epitope detector or an epitope anchor as claimed in claims 5 and 6. Suzuki et al. also indicates that there is a very sensitive antigen detection system has been developed (See pg. 885 column 1, first paragraph) and the method of Suzuki et al. has a 10^3-fold higher sensitivity (See pg. 885, column 2, first paragraph).

Applicants argue as filed 11/5/2002 and 8/23/2002 that the teachings of Suzuki et al. do not direct the correlation between the amount of signal and the amount of protein present as a quantitative detection method (See pg. 13 of the response filed 11/5/2002 and pg. 5 of the response filed 8/23/2002). However, the claim language does not require the limitation as to the correlation between the amount of signal and the amount of protein present as a quantitative detection method. Nevertheless, the method of Suzuki et al. is directed to quantify the antigen in sera since the detection method is quantifying the amount of target which is higher than zero or

lower than zero and Suzuki et al. disclose that the method has a 10^3-fold higher sensitivity (See pg. 885, column 2, first paragraph). In addition, as disclosed by Eberwine et al., the method of Eberwine et al. is for detecting a selected protein by immuno aRNA (See column, 2, lines, 37-50) and the presence and quantity of labeled RNA transcript is indicative of the amount of selected protein present (See column 4, lines 33-36 and columns 7-8, claims 1-2). Applicants further argue that the method of Suzuki et al. teach use of whole antibody in a method involving DNA amplification. The specification discloses using an antibody to couple with cDNA (See pg. 18, example 5). Thus, the teachings of Suzuki et al. suggest the limitations of claim 5

Therefore, one of ordinary skill in the art at the time of the instant invention would have been motivated to combine the teachings of Suzuki et al., and Eberwine et al. to make the system as claimed with a reasonable expectation of success because the system of Suzuki et al. has a 10^3-fold higher sensitivity (See pg. 885, column 2, first paragraph) and detect antigen in sera at a level below the detection limit of traditional ELISA method (See pg. 885, the Abstract), and Eberwine et al. disclose using labeled RNA to determine the amount of selected protein present in small amount (See column 4, lines 34-39). In addition, although none of the references above discloses a kit used for performing the quantification, one of ordinary skill in the at the time of the instant invention would have packed all components needed for the system as claimed because this was routine practice in the art at the time of the instant invention. It would have been prima facie obvious to make the system and kit as claimed.

8. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. (Jpn. J. Cancer Res., 1985, Vol. 86, pg. 885-889) in view of Eberwine et al. (5,922,553) as applied to claims 5-6 and 8-11 above, and further in view of Quentin-Millet et al. (4,965,205).

The teachings of Suzuki et al., and Eberwine et al. are set forth in section 7 above and Suzuki et al., and Eberwine et al. do not disclose using the epitope detector comprising hemagglutinin or polyhistidine as a universal epitope detector (See pg. 11, lines 31-35 of the specification).

Quentin-Millet et al. disclose using ELISA involving anti- filamentous hemagglutinin antibody to estimate the amount toxin antigen (See column 4, lines 26-30). The method of Quentin-Millet et al. produced a high yield toxin antigen which is detected by using ELISA involving anti- filamentous hemagglutinin antibody.

One of ordinary skill in the art at the time of the instant invention would have been motivated to combine the teachings of Suzuki et al., Eberwine et al. and Quentin-Millet et al. to make the system as claimed with a reasonable expectation of success because the system of Suzuki et al. has a 10^3-fold higher sensitivity (See pg. 885, column 2, first paragraph) and detects antigen in sera at a level below the detection limit of traditional ELISA method (See pg. 885, the Abstract), anti- hemagglutinin antibody has been used for detection in ELISA as taught by Quentin-Millet et al. (See column 4, lines 26-30) and Eberwine et al. disclose that the labeled RNA is to determine the amount of selected protein present in small amount (See column 4, lines 34-39). It would have been prima facie obvious to make the system and kit as claimed.

9. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

October 29, 2002

GARY BENZION
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600